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AUSTRALIA

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PATENT REQUEST : STANDARD PATENT

I, Ivonne Beatriz Buckley-Mendez being the person identified below as the Applicant and Nominated Person, request the grant of a Patent for an invention described in the accompanying complete specification.

Full application details follow:

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[54] Invention Title: Face Mask for use with Positive Airway Pressure Devices

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ALEXANDRIA NSW 2015

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DIVISIONAL APPLICATION DETAILS

[62] Original Petty Patent no: 661266

Dated this 28th day of September 1995

Ivonne Beatriz Buckley-Mendez

BY:


Patent Attorney for the Applicant

TO: THE COMMISSIONER OF PATENTS

1013/AF

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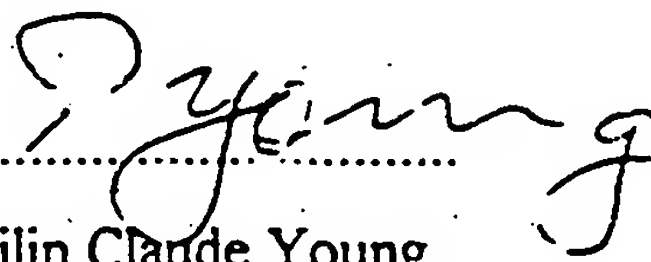
NOTICE OF ENTITLEMENT

I, Philip Claude Young, Registered Patent Attorney, of 225 Lawrence Street, Alexandria, New South Wales, 2015, being authorised by the applicant, state the following:

The nominated person/applicant is the actual inventor.

The nominated person/applicant is the patentee of the original petty patent.

Dated this 28th day of September 1995.


Philip Claude Young



AU9532914

(12) PATENT ABSTRACT (11) Document No. AU-A-32914/95
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FACE MASK FOR USE WITH POSITIVE AIRWAY PRESSURE DEVICES
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- (72) Inventor(s)
IVONNE BEATRIZ BUCKLEY-MENDEZ
- (74) Attorney or Agent
WILSON & YOUNG, Patent and Trade Mark Attorneys, P O Box 553, ALEXANDRIA NSW 2015
- (57) Claim

1. A face mask for use on a patient using Continuous Positive Airway Pressure (CPAP) devices, Intermittent Positive Airway Pressure devices (IPAP) devices, Bi-Level Positive Airway Pressure devices (BI-PAP) devices and other ventilator devices, said face mask comprising a mask portion having securing means to enable said mask portion to be secured to the patient's face with said mask portion partly secured under the patient's chin and partly secured across the patient's mouth so that in use the mask portion supports the patient's chin and mouth to prevent the patient's mouth from opening due to positive air pressure in the patient's air passages and therefore prevent air loss through the patient's mouth, wherein said mask portion includes a chin support portion and a mouth support portion, with the mouth support portion comprising two extensions from the chin portion, wherein in use the two extensions are crossed-over each other over the patient's mouth to form the mouth support portion.

9. A face mask for use on a patient using Continuous Positive Airway Pressure (CPAP) devices, Intermittent Positive Airway Pressure devices (IPAP) devices, Bi-Level Positive Airway Pressure devices (BI-PAP) devices and other ventilator devices, said face mask comprising a mask portion having securing means to enable said mask portion to be secured to the patient's face with said mask portion partly secured under the patient's chin and partly secured across the patient's mouth so that in use the mask portion supports the patient's chin and mouth to prevent the patient's mouth from opening due to positive air pressure in the patient's air passages and therefore prevent air loss through the patient's mouth.

FACE MASK FOR USE WITH POSITIVE AIRWAY PRESSURE DEVICES

The present invention relates to the use of Positive Airway Pressure devices, such as Continuous Positive Airway Pressure devices (known as CPAP devices), Intermittent Positive Airway Pressure devices (known as IPAP devices), Bi-Level Positive Airway Pressure devices (known as BI-PAP devices), and other ventilator devices and, in particular, to an improved mask which is used to support a patient's jaw to prevent their mouth from opening to thereby cause a leakage of air when using such devices and the like.

BACKGROUND TO THE INVENTION

Continuous Positive Airway Pressure devices (known as CPAP devices) are used with patients who suffer from sleep apnoea (suspension of breath when sleeping) and/or excessive snoring. The CPAP devices are used during treatment when the patient is asleep and generally include a pressurised air supply which is provided to the patient's air passages via apertures in a mask which covers the patients nose or nose and mouth. The air is supplied to the nose of the patient as it has been found that the patient responds better to the treatment when they are forced to breath through the nose and not the mouth. The air is pressurised to a pressure which is only slightly greater than atmospheric pressure but is sufficient to maintain the patient's air passages clear and thereby prevent sleep apnoea.

One problem which arises from this form of treatment is that the pressurised air which is used in the treatment has a pressure which is also sufficiently high enough to escape from the patient's air passages through the mouth during the treatment due to slackening of the patient's jaw during relaxed wakefulness and sleep or jaw abnormalities. The loss of air through the patient's mouth during treatment reduces the effectiveness of the treatment and therefore it is desirable to devise an apparatus which substantially prevents the leakage of air from the mouth during treatment. There are similar effects when using other ventilator devices as mentioned above.

OBJECT OF THE INVENTION

It is therefore an object of the invention to provide an improved face mask apparatus and method of use with Positive Airway Pressure devices which substantially overcomes or

ameliorates the above mentioned problem with treatment. At the very least, the invention provides an alternative to known apparatus and methods used in the treatment of sleep apnoea and/or excessive snoring.

DISCLOSURE OF THE INVENTION

5 According to one aspect of the invention there is disclosed a face mask for use on a patient using Continuous Positive Airway Pressure (CPAP) devices, Intermittent Positive Airway Pressure devices (IPAP) devices, Bi-Level Positive Airway Pressure devices (BI-PAP) devices and other ventilator devices, said face mask comprising a mask portion having
10 securing means to enable said mask portion to be secured to the patient's face with said mask portion partly secured under the patient's chin and partly secured across the patient's mouth so that in use the mask portion supports the patient's chin and mouth to prevent the patient's mouth from opening due to positive air pressure in the patient's air passages and therefore prevent air loss through the patient's mouth, wherein said mask portion includes a chin support portion and a mouth support portion, with the mouth support portion comprising
15 two extensions from the chin portion, wherein in use the two extensions are crossed-over each other over the patient's mouth to form the mouth support portion.

In one preferred form, the mask portion of the face mask is formed in one piece and is made from stretchable material which is also recoverable. The securing means preferably comprise a plurality of stretchable elongate recoverable straps which extend from the mask portion, to
20 secure the mask portion against the patient's face. In one preferable form the straps extend from the mask portion and have attachment devices located on their free ends so as to be attached to either another one of the straps or to a further attachment device. Such a further attachment device can be associated with a separate piece of equipment being used by the patient.

25 In one preferred form, the mask portion which is formed in one piece, includes a chin support portion and a mouth support portion. In one preferred form of the mouth support portion of the one piece mask portion the mouth support comprises two rabbit-ear like

extensions from the chin portion. In this preferred form, the straps are connected to both sides of the chin support portion and to the free ends of the two rabbit-ear like extensions and in use the two rabbit-ear like extensions are crossed-over each other over the patient's mouth to form the mouth support portion. Another preferred form of the mouth support portion is that it has a substantially similar shape to that of the chin support portion.

In another preferred form, the mask portion is formed from two separate pieces with a chin support portion forming one piece and a mouth support portion forming the other piece. The chin support portion and the mouth support portion are adjustably releasably fixable to each other to form the mask portion. As the two pieces are adjustable in their positional relationship, the mask portion can be adjusted for use with patients having a variety of different size heads.

In some preferred forms, the mask portion is made from more than one layer of material, and in the preferred form is made from two outer layers of stretchable cotton based material with a stretchable synthetic material sandwiched in between, or two non-stretchable cotton based materials.

In another preferred form, the mask portion is made from a non-stretchable material and preferably has a chin support portion which is adjustable in width. In a further preferred form the chin support portion is split to enable chin to protrude.

In another preferred form, the mask portion has a plurality of strap means to secure a nose mask apparatus to the mask portion, thus enabling the nose mask apparatus to be fitted to the patient when fitting the face mask, if desirable. The plurality of strap means can be used to fit the nose mask apparatus following the fitting of the face mask.

BRIEF DESCRIPTION OF THE DRAWINGS

Some embodiments of the present invention will now be described with reference to the 25 drawings in which;

Fig. 1 is a front view of a face mask of a first embodiment.

Fig. 2 is a front view of a patient's head shown with the face mask of Fig. 1 in position;

Fig. 3 is a side view of the patient's head as shown in Fig. 2;

Fig. 4 is a front view of a face mask of a second embodiment;

Fig. 5 is a front view of a patient's head shown with the face mask of Fig. 4 in position;

5 Fig. 6 is a side view of the patient's head as shown in Fig. 4;

Fig. 7 is a front view of a face mask of a third embodiment;

Fig. 8 is a front view of a patient's head shown with the face mask of Fig. 7 in position;

Fig. 9 is a side view of the patient's head as shown in Fig. 7;

Fig. 10 is a rear view of the patient's head as shown in Fig. 7;

10 Fig. 11 is a front perspective view of a face mask of a fourth embodiment shown with the two parts of its mask portion separated;

Fig. 12 is a front perspective view of a face mask of Fig. 11 shown with the two parts of its mask portion joined together;

Fig. 13 is a front view of a patient's head shown with the face mask of Fig. 11 in position;

15 Fig. 14 is a side view of the patient's head as shown in Fig. 11;

Fig. 15 is a front view of a face mask of a fifth embodiment;

Fig. 16 is a rear view of the face mask of Fig. 15;

Fig. 17 is a front view of a patient's head shown with the face mask of Fig. 15 in position illustrated with a nose mask associated with a respiratory device shown in position;

Fig. 18 is a side view of the patient's head as shown in Fig. 17; and

Fig. 19 is a rear view of the patient's head as shown in Fig. 17.

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BEST MODE OF CARRYING OUT THE INVENTION

A face mask 10 of a first embodiment, for use with CPAP devices is illustrated with respect to Figs. 1-3, and includes a mask portion 11 having four elongate stretchable straps 12 extending therefrom. In this embodiment the straps 12 are sewn to the mask portion 11 but can be connected in any suitable way.

10 The mask portion 11 is formed in a single piece and is made from a stretchable material such as lycra (Trade Mark). In the preferred form the mask portion 11 comprises three layers of material, with the outer layers being made from a cotton based lycra™ and the sandwiched layer being made from a synthetic based lycra™. The reasoning for this preferred construction is that the cotton outer layers help minimise perspiration thus minimises the
15 mask portion from either slipping or sticking to the patient's face during use.

The straps 12 are made from an elasticised material and each has a tab 13 of velcro® material attached thereto its free end. A first pair of the straps 12 extend from sides 14 of a chin support portion 15 of the mask portion 11, while a second pair of straps 12 extend from ends 16 of a pair of rabbit-ear like extensions 17 which form a mouth support portion 18 of the
20 mask portion 11. The tabs 13 of velcro® material of both the pairs of straps 12 complement each other such that the pairs of straps 12 are securable together as shown in Fig. 4.

The mask portion can be made from a non-stretchable material, which can be a cotton based material. When made from a non-stretchable material only two pieces of non-stretchable material are used. Even though non-stretchable material is less able to contour to the shape
25 of the patient's face, there should be additional strength using such materials. Similarly the straps can be made from a non-elasticised material.

The CPAP device (not illustrated) with which the face mask 10 is used in conjunction generally includes a nose mask which is substantially sealed against the patient's skin. An air supply is pumped under continuous positive pressure through a tube to the nose mask. The nose mask is usually made from plastics material and is secured to the patient's head with 5 straps.

The face mask 10 is fitted to the patient as shown in Figs. 2-3 the chin support portion 15 being fitted under the patient's chin and the first pair of straps 2 being joined by the fixing together of the complementary velcro® tabs 13. It is seen that due to the position of the first pair of straps 12 and the patient's head structure that the straps 12 are joined adjacent the top 10 of the patient's head. This has the effect that the patient's chin is supported and urged in an upwards direction.

The pair of rabbit-ear like extensions 17 are then drawn across the patient's mouth such that the two extensions 17 cover the patient's mouth as seen in Figs. 2-3. The second pair of straps 12 are then joined by fixing their complementary velcro® tabs 13 together. In this case the second pair of straps 12 pass around the back of the patient's head. The force of the straps 12 and the material in the mask portion 11 has the effect that the mouth and face is supported and covered to help prevent air leakage through the mouth, when the patient is undergoing treatment. In this particular embodiment, the pair of extensions 17, when crossed over, each provide a substantial force to maintain the mouth closed under the positive air pressure within the patient's air passages as well as preventing "puffiness" in the patient's cheeks.

A face mask 20 of a second embodiment is illustrated in Figs. 4-6. The face mask 20 has a similar construction to that of the face mask 10 of the first embodiment, with the face mask 20 having a mask portion 21 and four stretchable elongate straps 22 attached to the mask portion in a similar manner. The straps 22 each have velcro® tabs 23 sewn to their free ends. The straps 12 extend from the sides 24 of a chin support portion 25 and from the ends 26 of a pair of rabbit-ear like extensions 27 which form a mouth support portion 28. In this embodiment, the mask portion 21 is made from a non-stretchable cotton material as it may be preferable for some patients. Other non-stretchable materials can be used if desired.

As the material is non-stretchable, the chin support portion 25 has two pairs of mating tongue pieces 29 which are fixed together using velcro® tabs 23a which are sewn on each tongue piece 29. There are two pairs of tongue pieces 29 as one pair is positioned under the patient's chin while the other pair is position at the front of the patient's chin. In effect there is a split in the chin support portion 25 so that the chin support portion 25 has a snug fit with the chin. This is required as the material is non-stretchable. The tongues pieces 29 are adjustable in their relationship with its corresponding piece 29 and therefore the chin support portion 25 is adjustable in its width to fit to the patient's facial structure. The mask portion 21 in this embodiment is actually in two pieces which are connectable using the velcro® tabs 10 23a.

The face mask 20 is fitted to the patient in a similar manner to that of the mask 10 of the first embodiment, however in this case the adjustable chin support portion is adjustably fitted to the patient for the desired fit. The face mask 20 acts in the same manner as that of the first embodiment.

15 A face mask 30 of a third embodiment is illustrated in Figs. 7-10. This face mask 30 has a mask portion 31 made in one piece and is made from stretchable material in the same manner as the first embodiment. The shape of the mask portion 31 is such that it is of a general I-shape with a chin support portion 35 being formed from the bottom and a mouth support portion 38 being formed from the centre of the mask portion 31. Two pairs of straps 32 20 extend from the side extensions 34 of the I-shaped mask portion 31 and are used in a similar manner to those of the previously described embodiments in that there are velcro® tabs 33 located at their free ends.

This face mask 30 is fitted, firstly by placing the chin support portion under the patient's chin and in this embodiment which uses an alternative fixing method, by securing the velcro® 25 tabs 33 to a larger complimentary velcro® tab 33a as shown. The other straps 32 are then also secured to the larger complimentary velcro® tab 33a (which can be attached to CPAP device headgear) ensuring enough pressure is applied by the mask portion 31 to the patient to maintain correct treatment. The straps 32 are adjustable in their positioning and tension that the mask 30 is fitted individually to fit the patient's facial structure.

A face mask 40 of a fourth embodiment is illustrated in Figs. 11-14. This face mask 40 has a two-piece mask portion 41 made up from a chin support portion 45 and a mouth support portion 48. These two portion 45 and 48 are able to be adjustably fixed together using complimentary velcro® tabs 53a which are sewn on to mating surfaces of the two portions 45 and 48.

The face mask 40 has an alternative system of straps to those of the previously described embodiments which includes a pair of straps 42a extending from each of the two portions 45 and 48 of the mask portion 41. These straps 42a are sewn together at their free ends and a velcro® tab 43 is located at their junction. Another pair of straps 42b are also sewn together with complimentary velcro® tabs 43a being located at their junction. In this case there are two half loops of straps to be secured at the back of the patient's head.

This face mask 40 is fixed to the patient's head in a similar manner to the previously described embodiments in that the chin support portion 45 and the mouth support portion 48 are applied to the relevant positions. The adjustability of the connection between the chin support portion 45 and the mouth support portion 48 is such that the mask 40 is applicable with a varying tension and pressure.

A face mask 60 of a fifth embodiment is illustrated in Figs. 15-19. The face mask 60 is used in conjunction with a nose mask 80 and a tube 81 as shown in Figs. 17-19. The face mask 60 is of a different construction to the previously described embodiments in that the face mask 60 is of integral form with various parts being joined together by means of complementary velcro® tabs (to be described in detail later) when fitted to the patient's head. The nose mask 80 is connected to the face mask 60 by releasable straps 82 and is thus able to be connected to the face mask 60 when it is being fitted to the patient. This enables the face mask 60 and nose mask 80 to be fitted at the same time which assists in a better fit as well as decreasing the time consumed during the fitting procedure, which is important, for example, if a large number of patients are to be fitted with the masks 60 and 80 in a clinic.

As best seen in Figs. 15 and 16, the face mask 60 includes a mask portion 61 with a number of complementary velcro® tabs and the nose mask straps 82 attached thereto. The mask portion 61 can be made from a stretchable or non-stretchable material and includes a top section 62, two strap sections 63, two side sections 64 and two bottom extensions 65.

The top section 62 fits on to the top of the patient's head while the two strap sections 63 are joined together by means of complementary velcro® tabs 63a at the back of the patient's head as shown in Fig. 19. The top section includes a central arm 62a and two outer arms 62b. The central arm 62a has a large velcro® tab 62c while the other arms 62b have 5 complementary velcro® tabs 62d attached thereto at their free ends. The complementary velcro® tabs 62c and 62d allow the top section 62 to be fitted as shown in Figs. 17-19 with the top section following the contour of the patient's head. The complementary velcro® tabs 62c and 62d can be joined prior to being fitted to the patient if the size of the patient's head is known or the mask 60 has been previously fitted.

10 The two side sections 64 as shown fitted to the side of the patient's head with the corresponding lower parts of the side sections 64 being joined together at the chin using complementary velcro® tabs 64a and 64b. The tab 64b actually passes under the patient's chin and forms a chin support portion 66 when so positioned.

The two bottom extensions 65 which extend inwardly from the base of the side sections 64 15 correspond to the rabbit ear extensions of the previously described embodiments. The extensions 65 are used to cover the mouth as shown in Figs. 17-19 and as such form a mouth support portion 68 in a similar manner to the previously described embodiments. The extensions 65 each have a velcro® tabs 65a positioned at their free ends, the velcro® tabs 65a being releasably attached to complementary velcro® tabs 64c positioned on the side 20 sections 64.

When all the aforescribed connections are made the fitting of the mask 60 is completed, except for any minor adjustments which can be made for patient comfort or to provide a better fit. It is noted that all the connections are adjustable.

As previously described, the nose mask 80 is joined to the face mask 60 by means of the 25 releasable straps 82. The releasable straps 82 are joined either to the inwardly facing sides of the top section 62 and side sections 64. The straps 82 pass through existing slots 83 in the nose mask 80. It is noted that one of the slots is formed in an arm 84 which has a pad 85 which in turn abuts against the patient's forehead when fitted. This is a further feature.

Each strap 82 has at its free end a velcro® tab 82a which is complementary to the velcro® tabs 62c and 64c on the top section 62 and side sections 64, respectively. This connection of the straps 82 is therefore adjustable and can be made before or after the masks 60 and 80 are fitted.

5 It is seen from Figs. 17-19 that the tube 81 is sealingly connected to the nose mask 80 and its most convenient position is over the top of the patient's head. The tube 91 is held in this position by a holding strap 84 which is connected to the top section 62.

This embodiment allows the connection of the nose mask 80 to the face mask 60 so that the ventilator equipment can be easily utilised with most comfort and benefit to the patient.

10 It is also noted that the mask portion 61 can be made from any suitable material, whether stretchable or not.

The foregoing describes only some embodiments of the invention and modifications obvious to those skilled in the art can be made thereto without departing from the scope of the present invention.

15 For example, the straps and velcro® connections can be replaced by any suitable securing method or device which enables the same resulting performance of the mask.

The claims defining the invention are as follows:

1. A face mask for use on a patient using Continuous Positive Airway Pressure (CPAP) devices, Intermittent Positive Airway Pressure devices (IPAP) devices, Bi-Level Positive Airway Pressure devices (BI-PAP) devices and other ventilator devices, said face mask
5 comprising a mask portion having securing means to enable said mask portion to be secured to the patient's face with said mask portion partly secured under the patient's chin and partly secured across the patient's mouth so that in use the mask portion supports the patient's chin and mouth to prevent the patient's mouth from opening due to positive air pressure in the patient's air passages and therefore prevent air loss through the patient's mouth, wherein said
10 mask portion includes a chin support portion and a mouth support portion, with the mouth support portion comprising two extensions from the chin portion, wherein in use the two extensions are crossed-over each other over the patient's mouth to form the mouth support portion.
2. The face mask according to claim 1, wherein the mask portion is formed in one piece, and
15 said securing means includes strap means being connected to both sides of the chin support portion and to the free ends of the two extensions.
3. The face mask according to claim 2, wherein the straps have attachment devices located on their free ends so as to be attached to either another one of the straps or to a further attachment device, wherein said further attachment device can be associated with a separate
20 piece of equipment being used by the patient.
4. The face mask according to claim 2, wherein said straps are a plurality of stretchable elongate recoverable straps.
5. The face mask according to claim 1, wherein the mask portion is made from more than one layer of material, and is made from two outer layers of stretchable cotton based material
25 with a stretchable synthetic material sandwiched in between, or two non-stretchable cotton based materials.

6. The face mask according to claim 1, wherein the mask portion is made from a non-stretchable material and has a chin support portion which is adjustable in width.
7. The face mask according to claim 6, wherein the chin support portion is split to enable the patient's chin to protrude.
8. The face mask according to claim 1, wherein a nose mask apparatus is securable to said mask portion in order that said nose mask can be fitted when fitting said face mask.
9. A face mask for use on a patient using Continuous Positive Airway Pressure (CPAP) devices, Intermittent Positive Airway Pressure devices (IPAP) devices, Bi-Level Positive Airway Pressure devices (BI-PAP) devices and other ventilator devices, said face mask comprising a mask portion having securing means to enable said mask portion to be secured to the patient's face with said mask portion partly secured under the patient's chin and partly secured across the patient's mouth so that in use the mask portion supports the patient's chin and mouth to prevent the patient's mouth from opening due to positive air pressure in the patient's air passages and therefore prevent air loss through the patient's mouth.
10. The face mask according to claim 9, wherein the mask portion is formed from two separate pieces with a chin support portion forming one piece and a mouth support portion forming the other piece.
11. The face mask according to claim 9, wherein the chin support portion and the mouth support portion are adjustably releasably fixable to each other to form the mask portion.

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DATED this TWENTYEIGHTH day of SEPTEMBER 1995

IVONNE BEATRIZ BUCKLEY-MENDEZ

Patent Attorneys for the Applicant

WILSON & YOUNG

ABSTRACT

FACE MASK FOR USE WITH POSITIVE AIRWAY PRESSURE DEVICES

A face mask (10) for use on a patient using Continuous Positive Airway Pressure (CPAP) devices, Intermittent Positive Airway Pressure devices (IPAP) devices, Bi-Level Positive Airway Pressure devices (BI-PAP) devices and other ventilator devices is disclosed. The face mask (10) comprises a mask portion (11) having securing straps (12) to enable the mask portion (11) to be secured to the patient's face with the mask portion (11) partly secured under the patient's chin and partly secured across the patient's mouth so that in use the mask portion (11) supports the patient's chin and mouth to prevent the patient's mouth from opening due to continuous positive air pressure in the patient's air passages and therefore prevent air loss through the patient's mouth.

Fig. 3

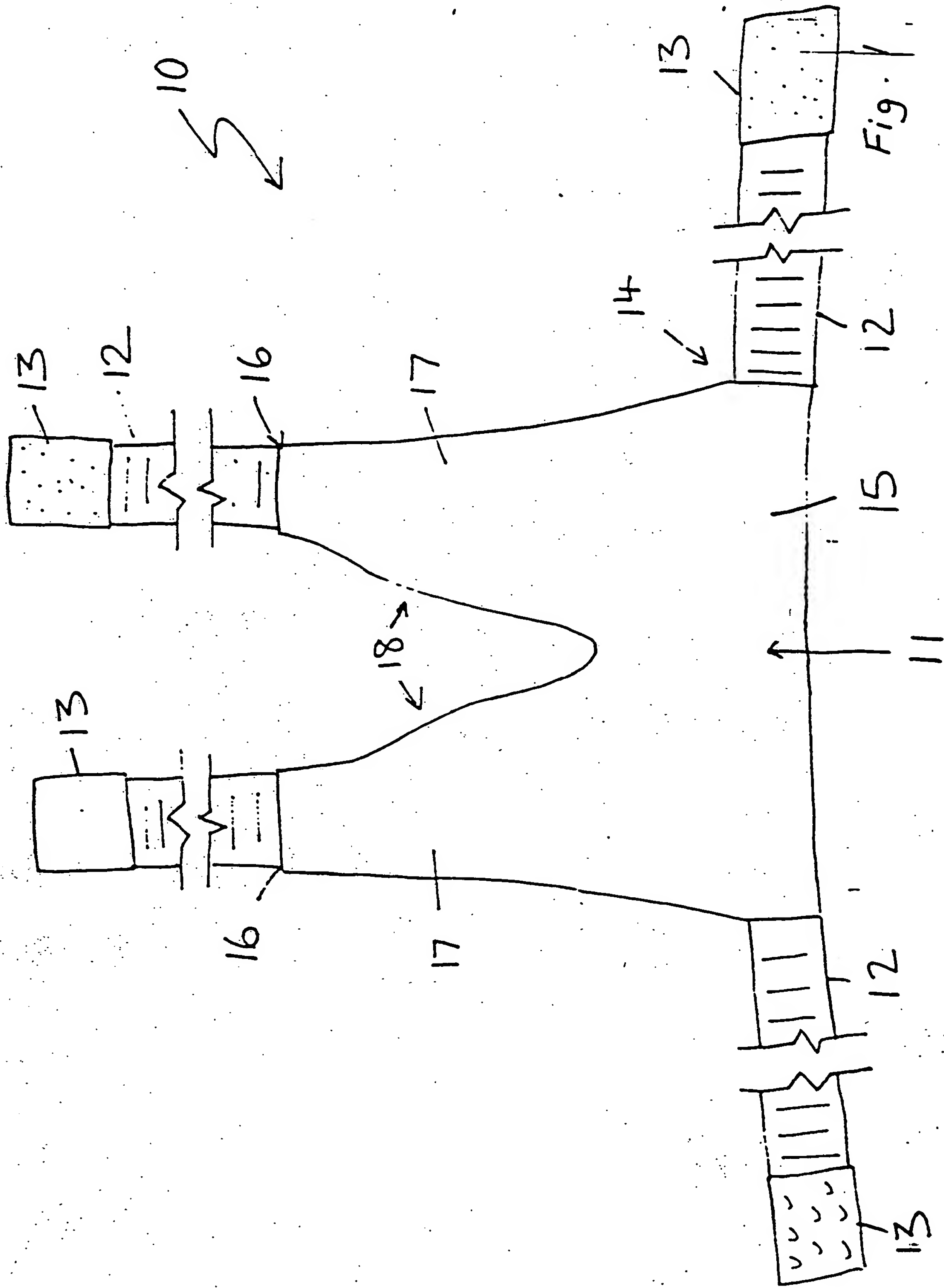


Fig. 1

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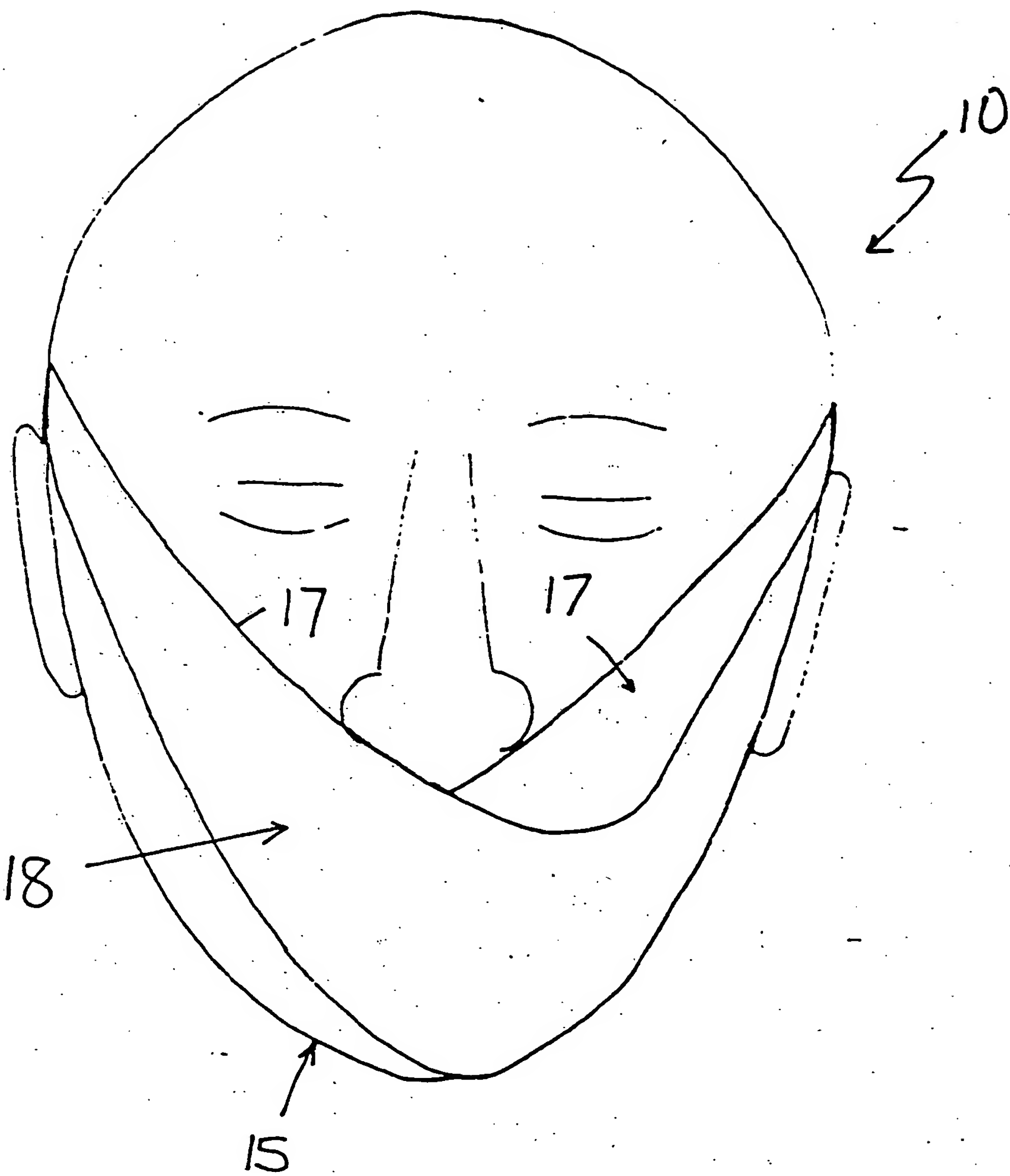
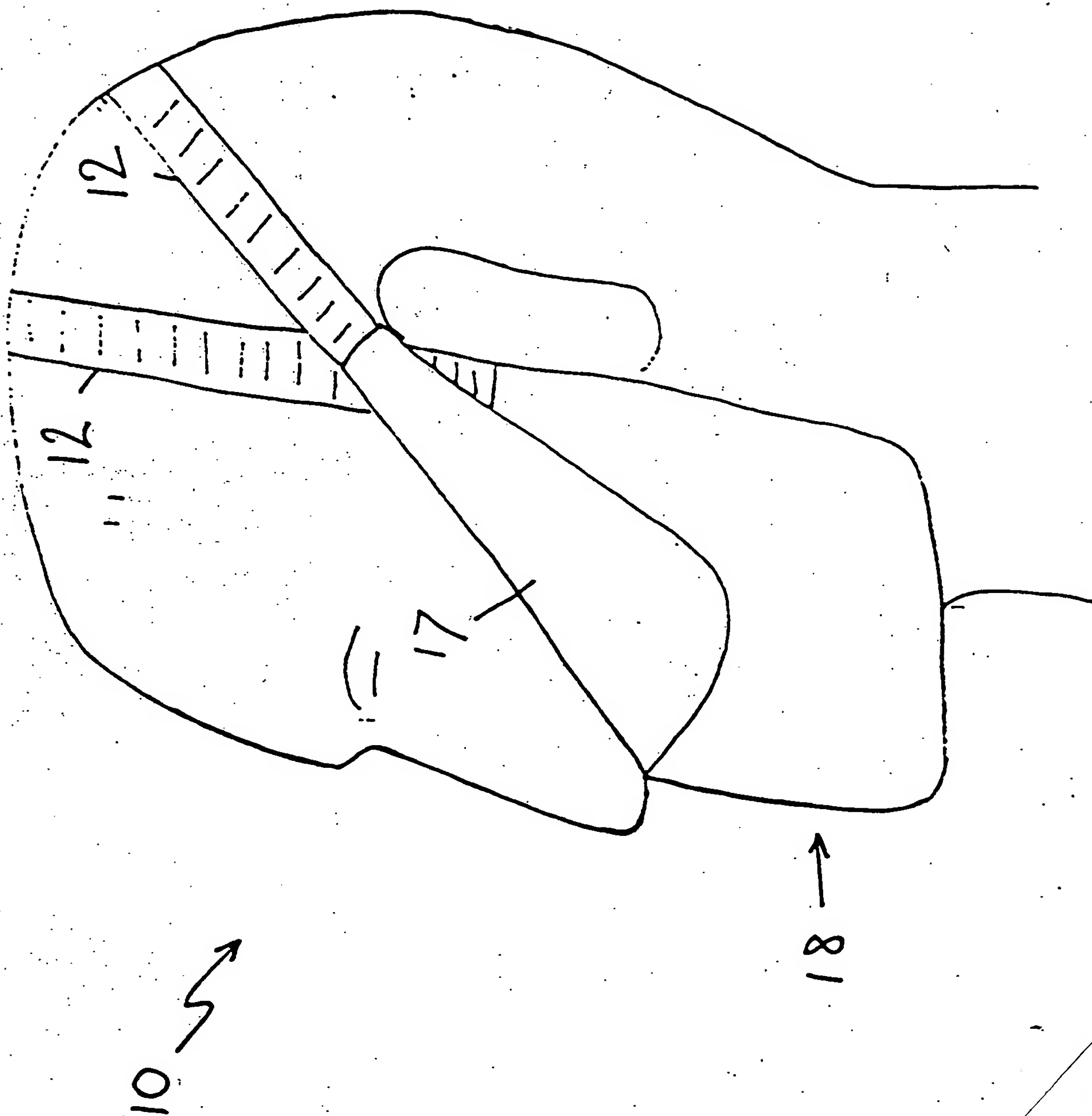


Fig. 2

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Fig. 3



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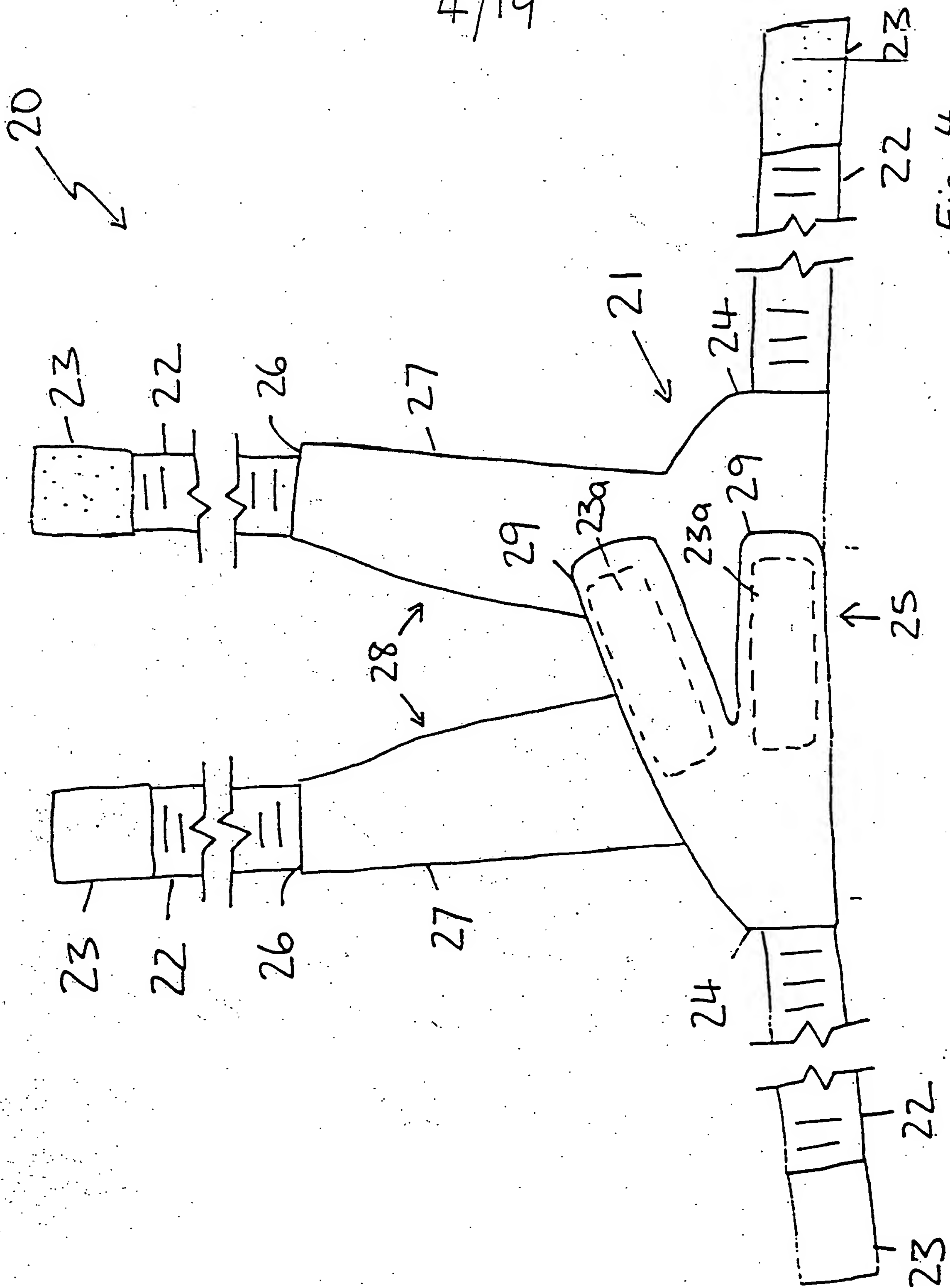


Fig. 4

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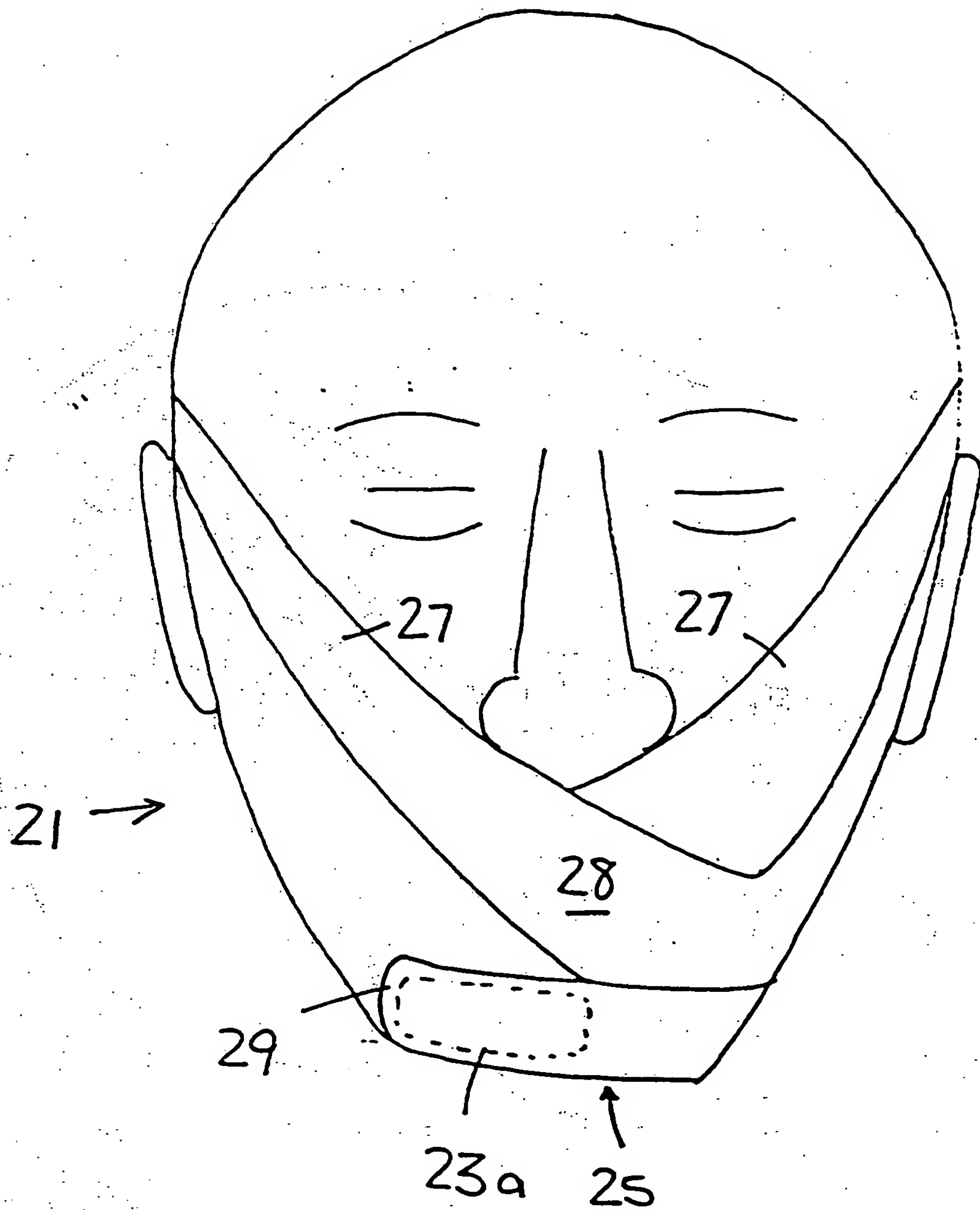
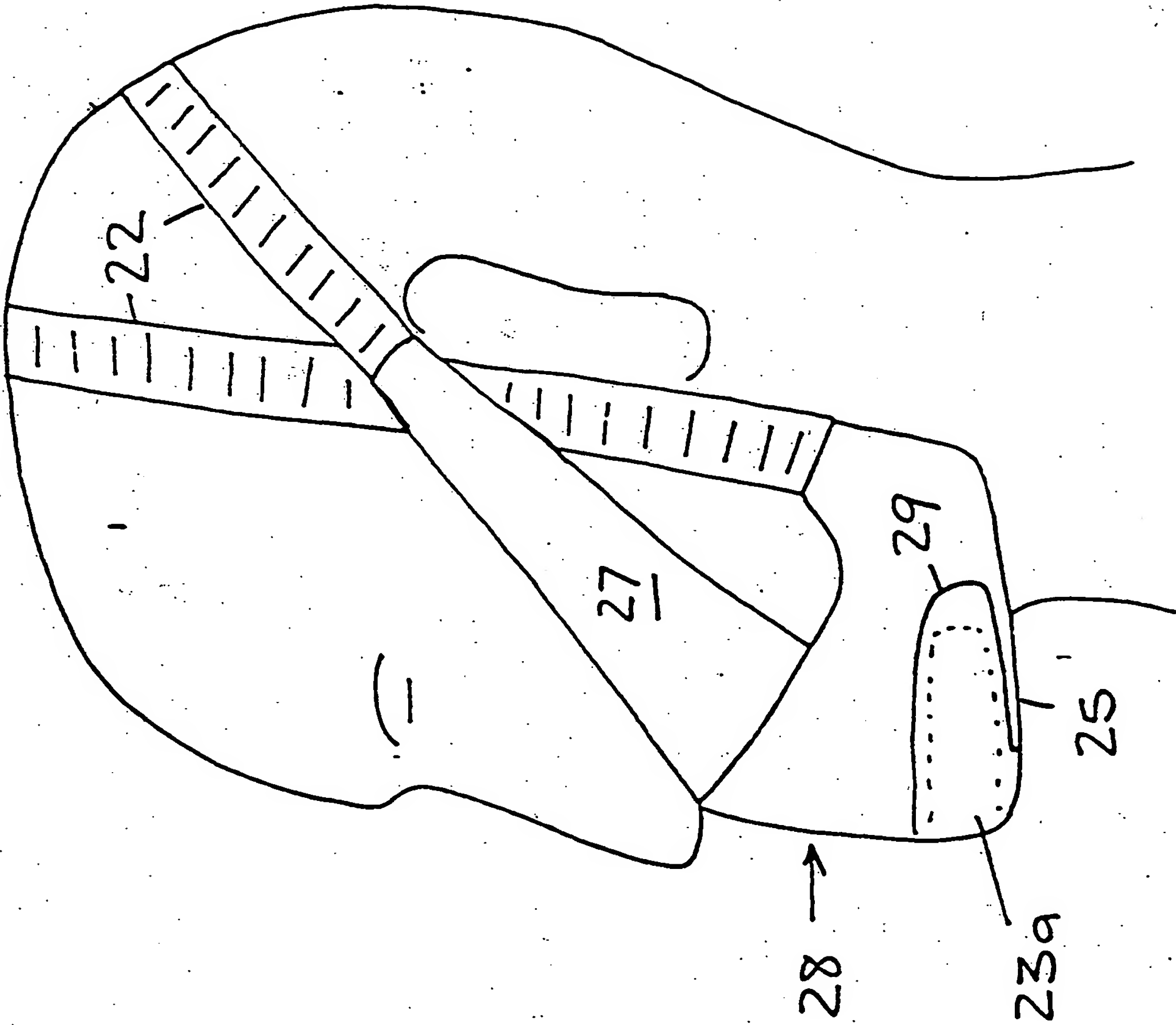


Fig. 5

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Fig. 6



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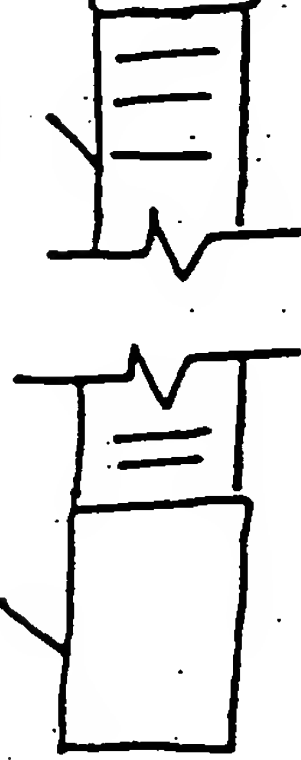


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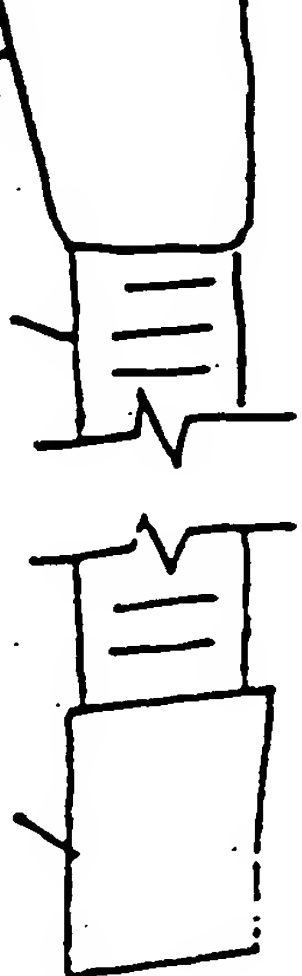


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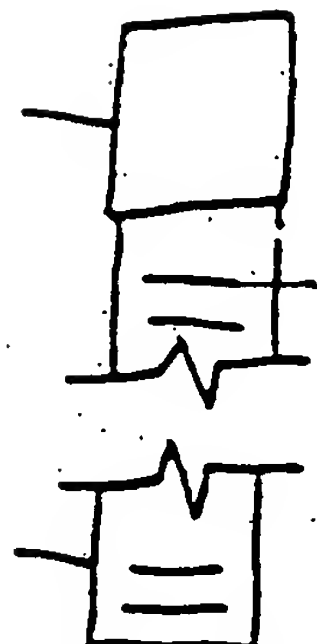


Fig. 7

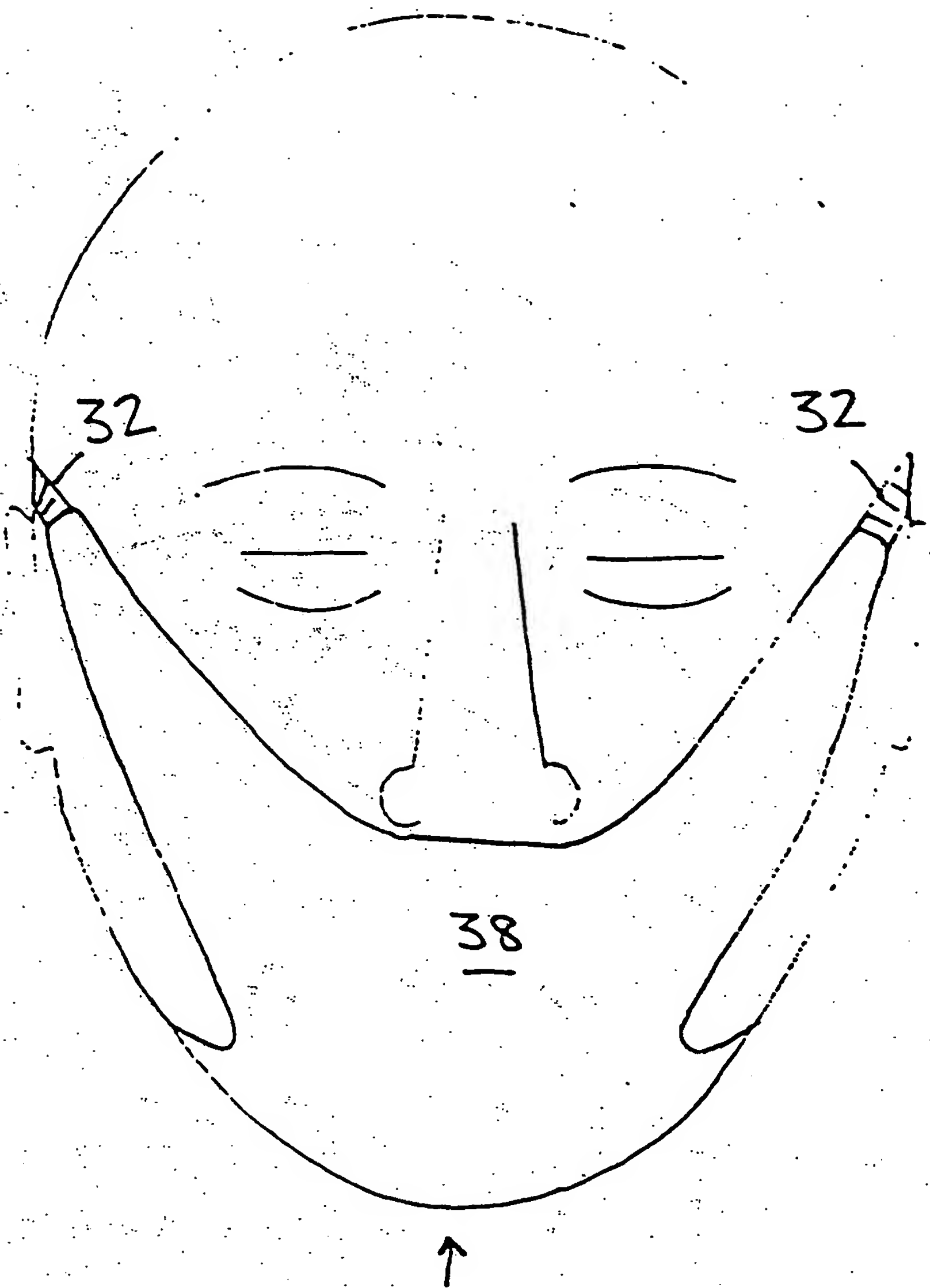
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Fig. 8

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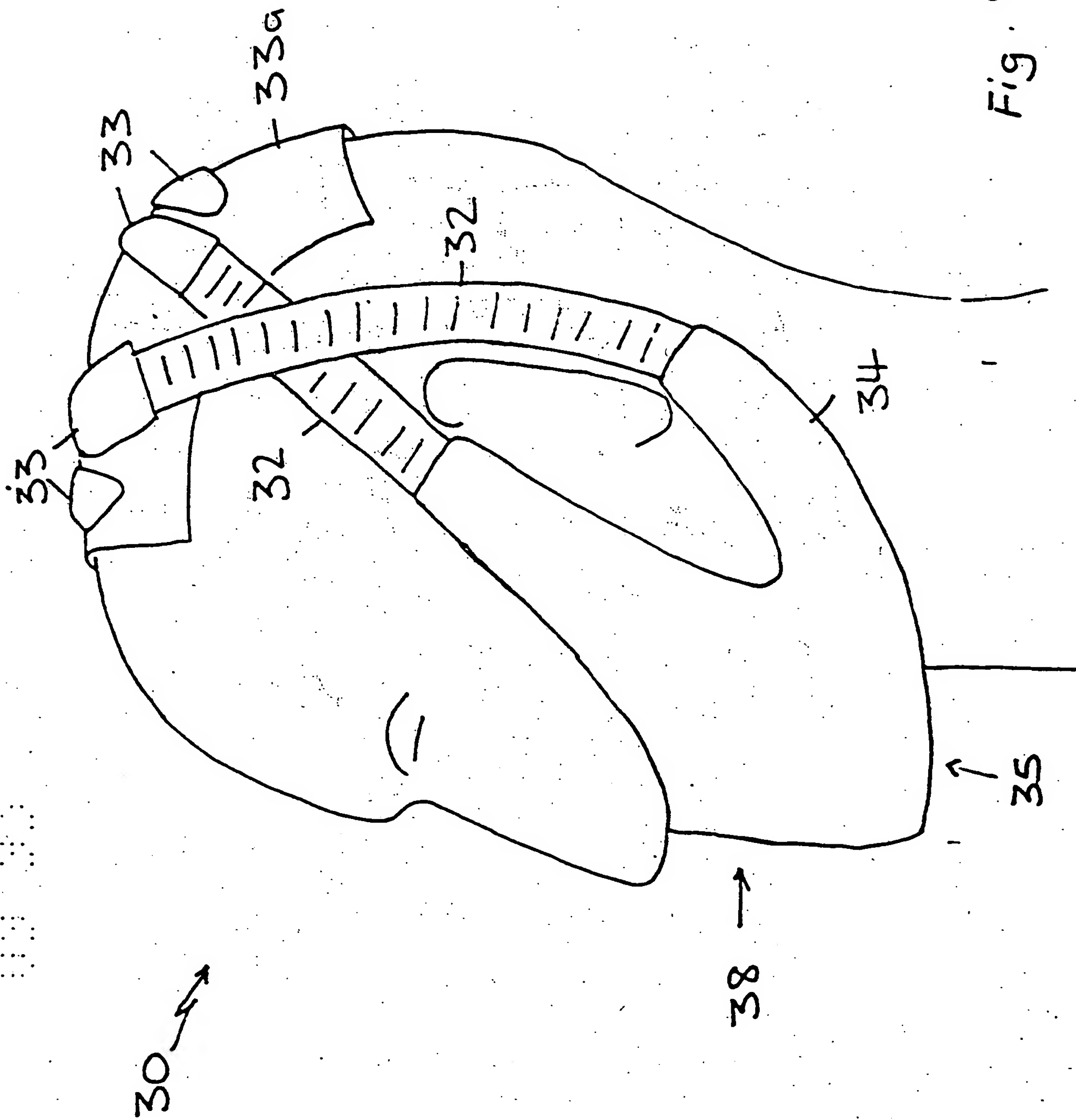


Fig. 9

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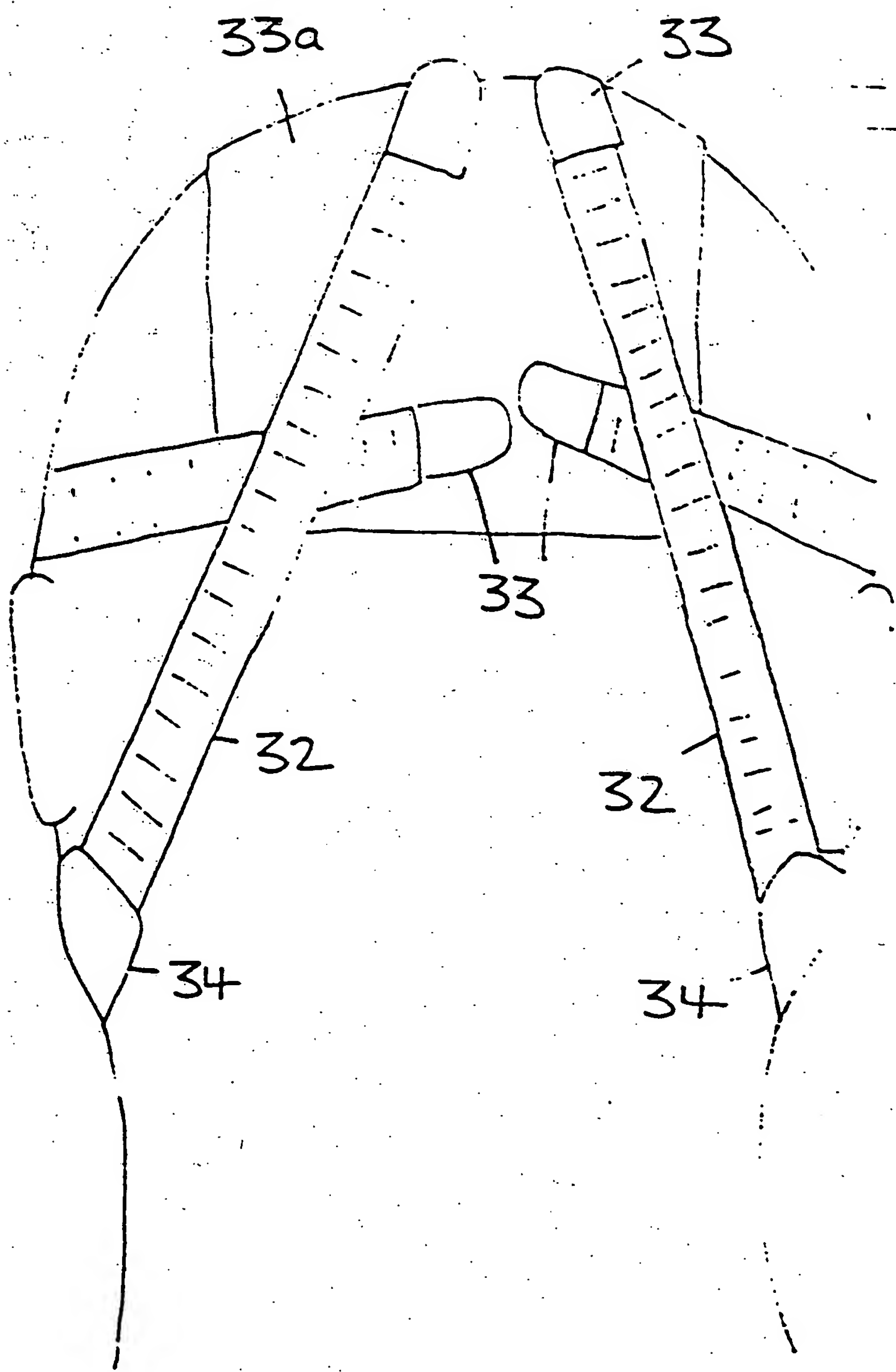
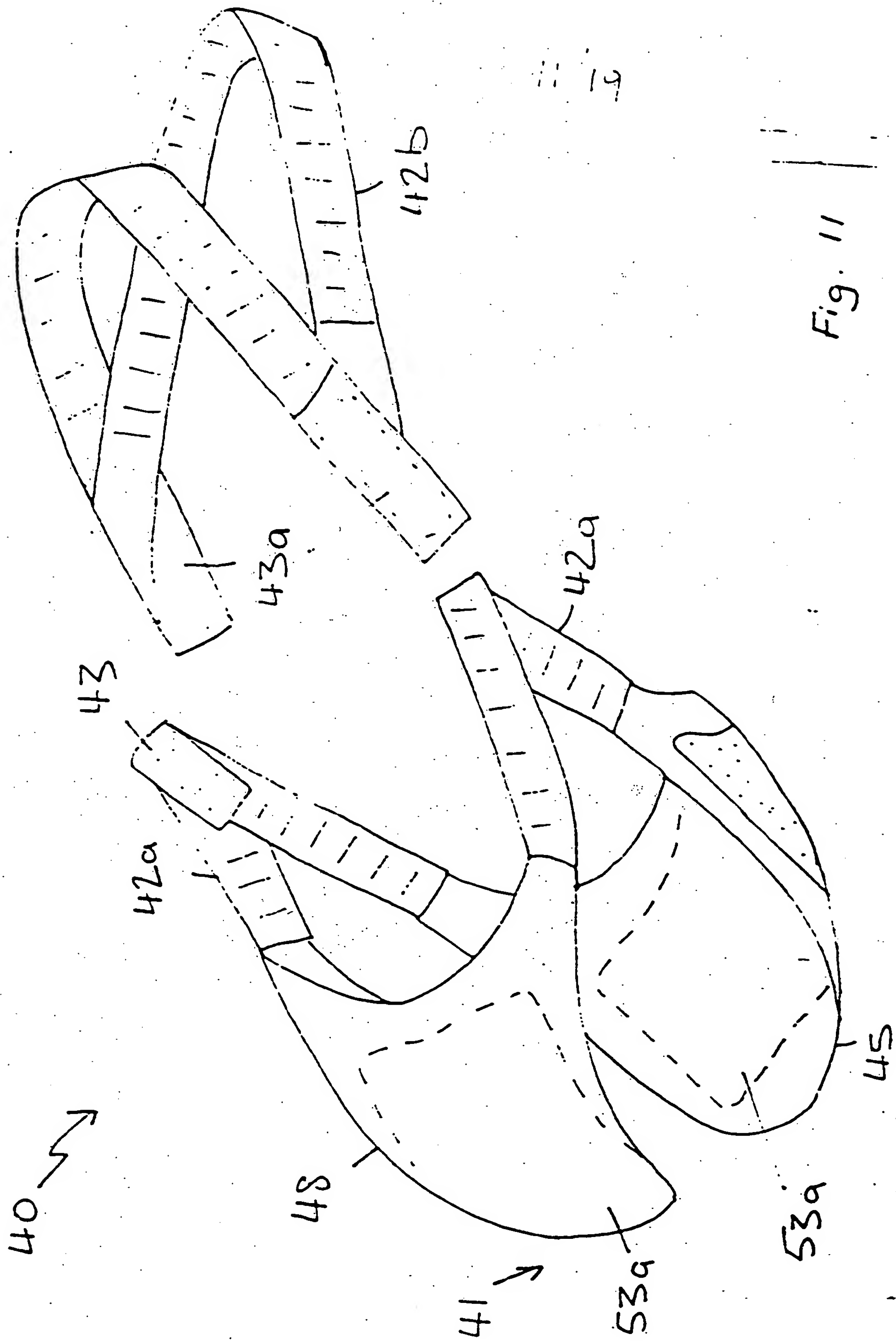


Fig. 10



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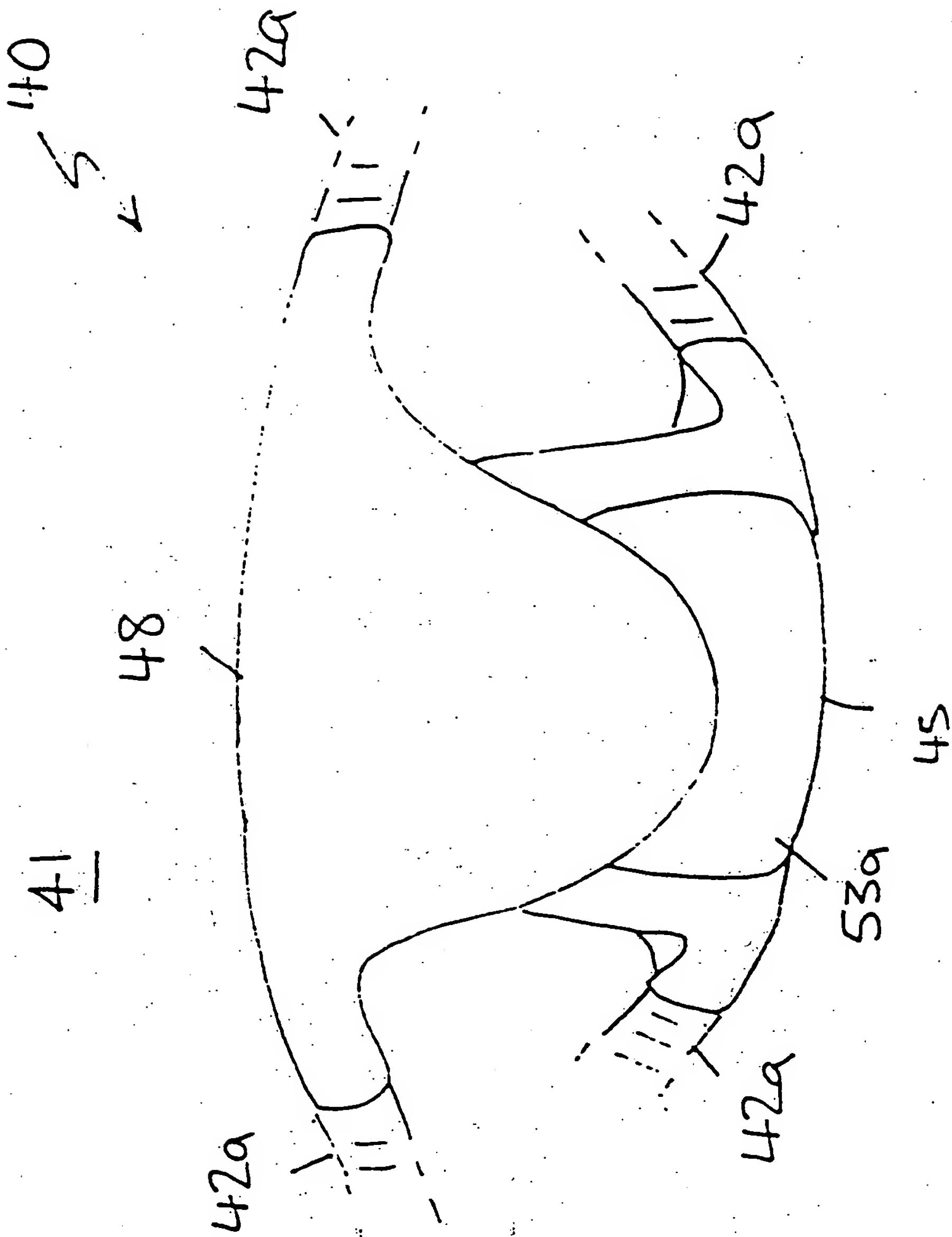


Fig. 12

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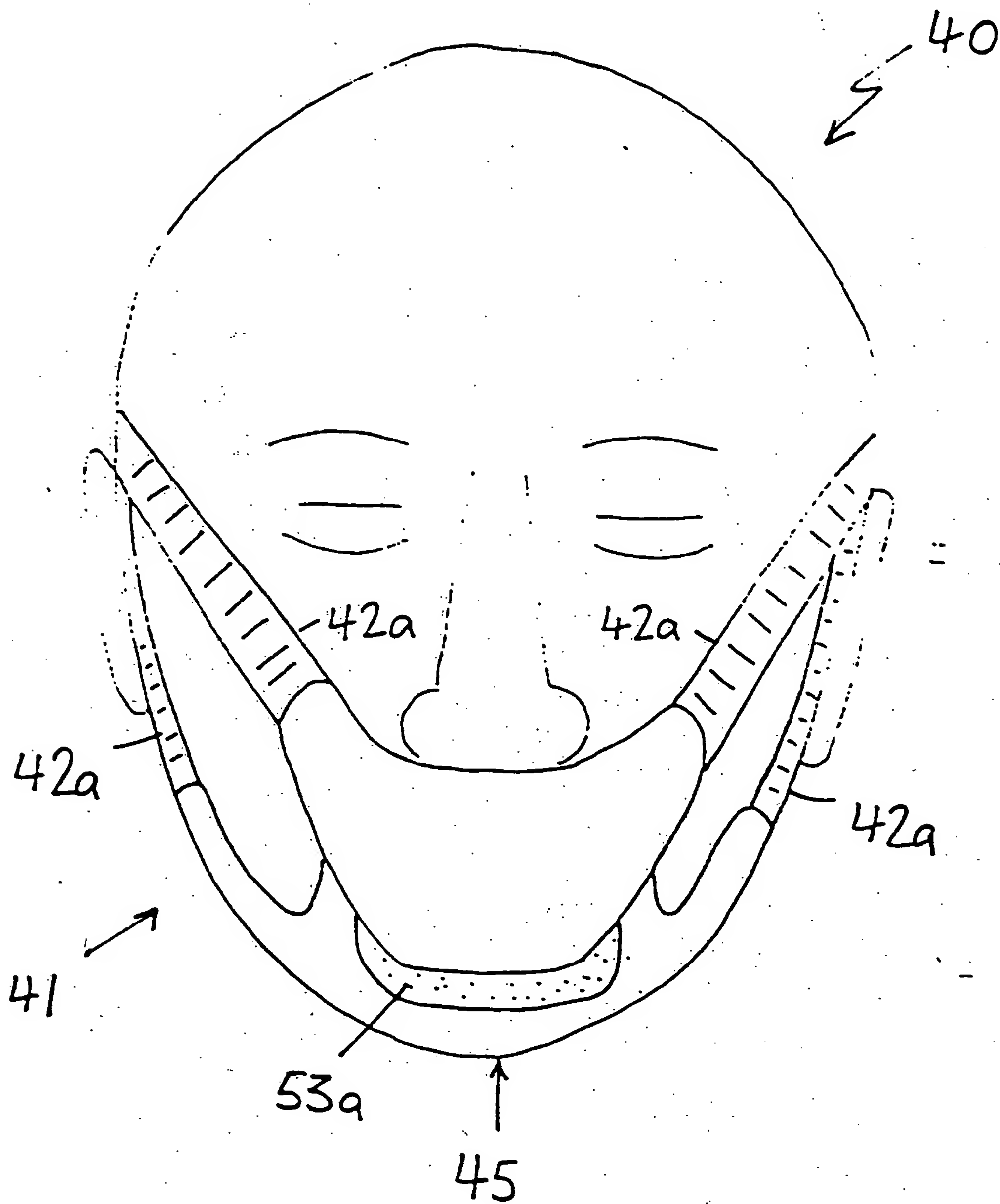
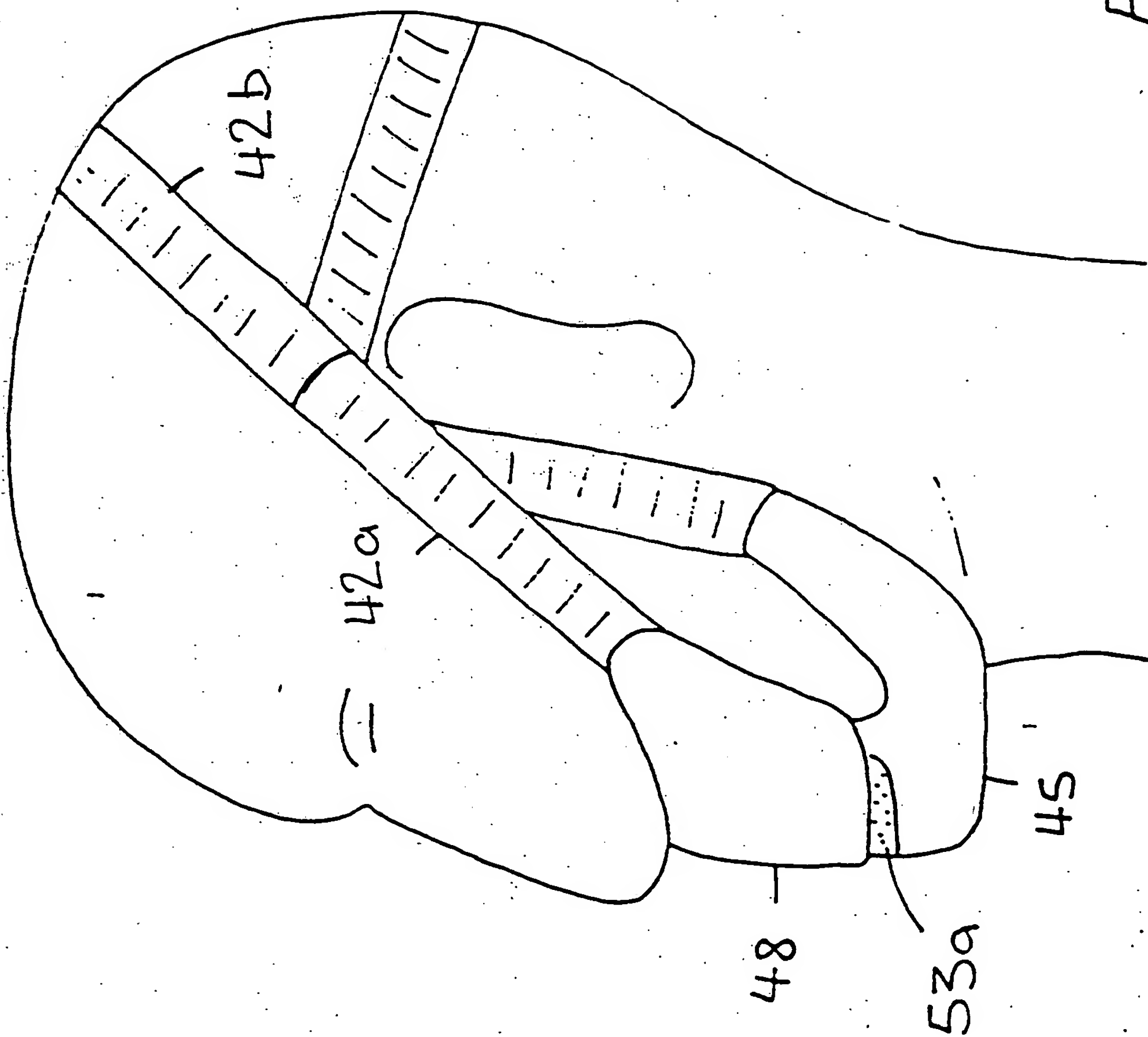


Fig. 13

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Fig. 14



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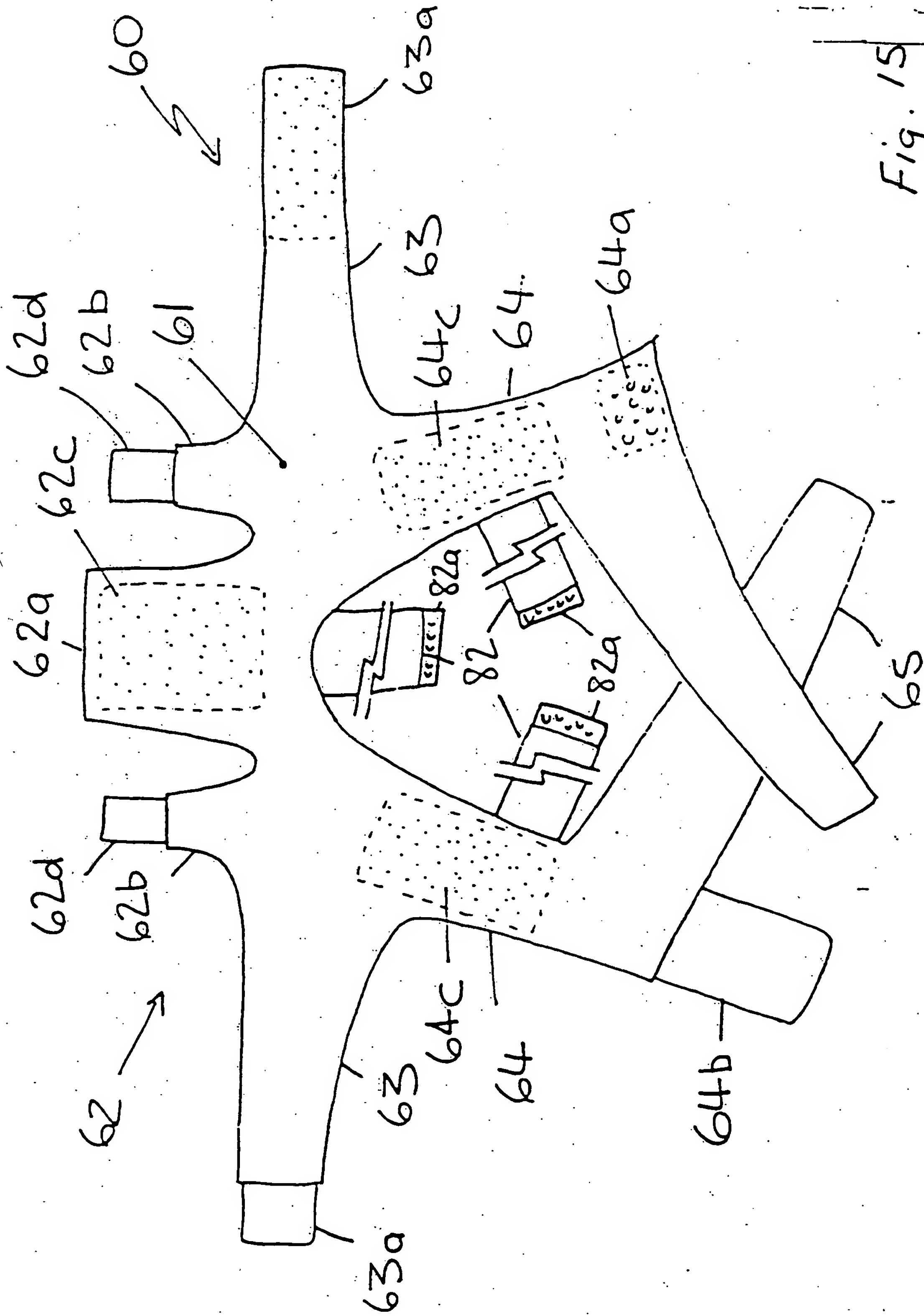


Fig. 15

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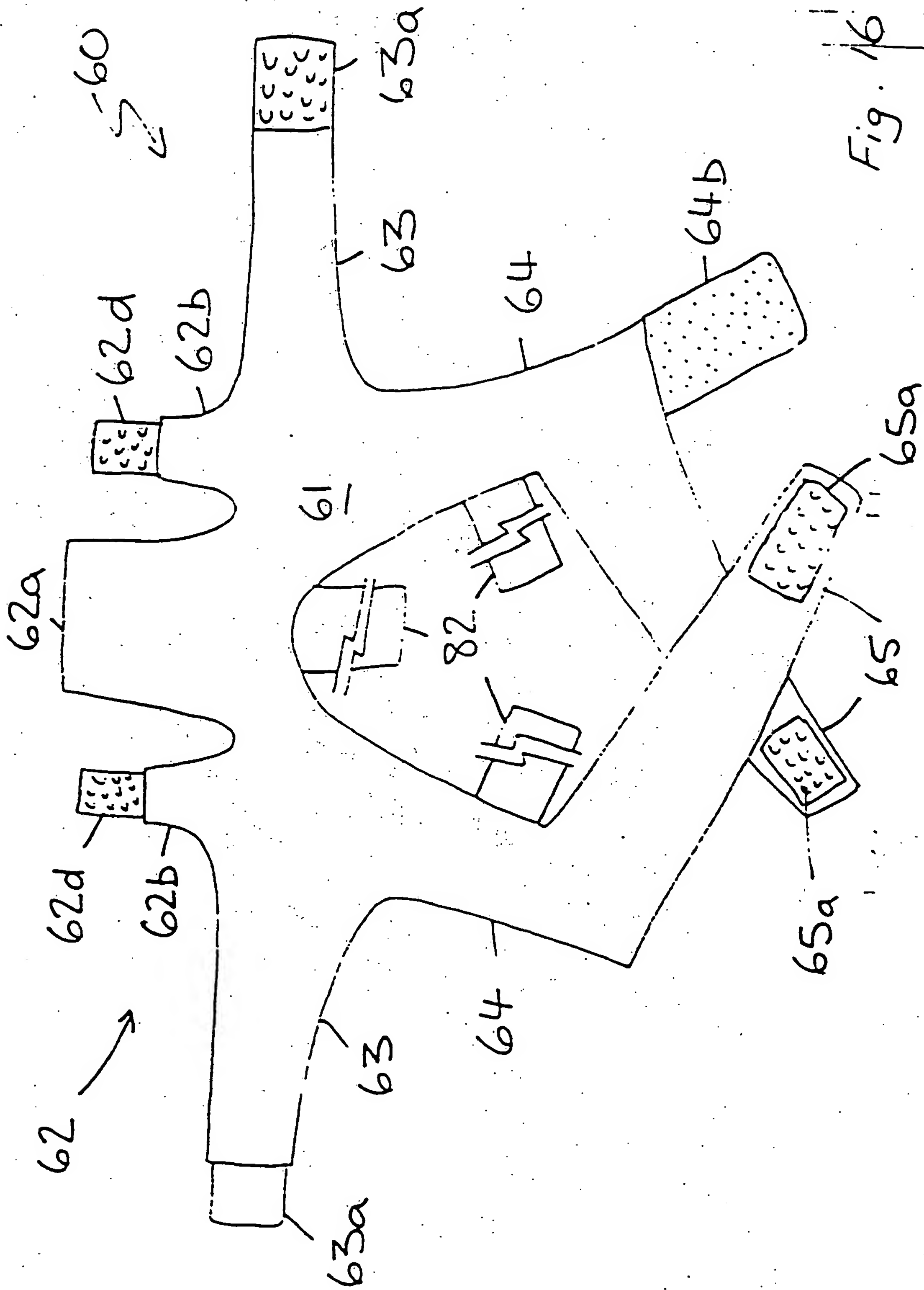


Fig. 16

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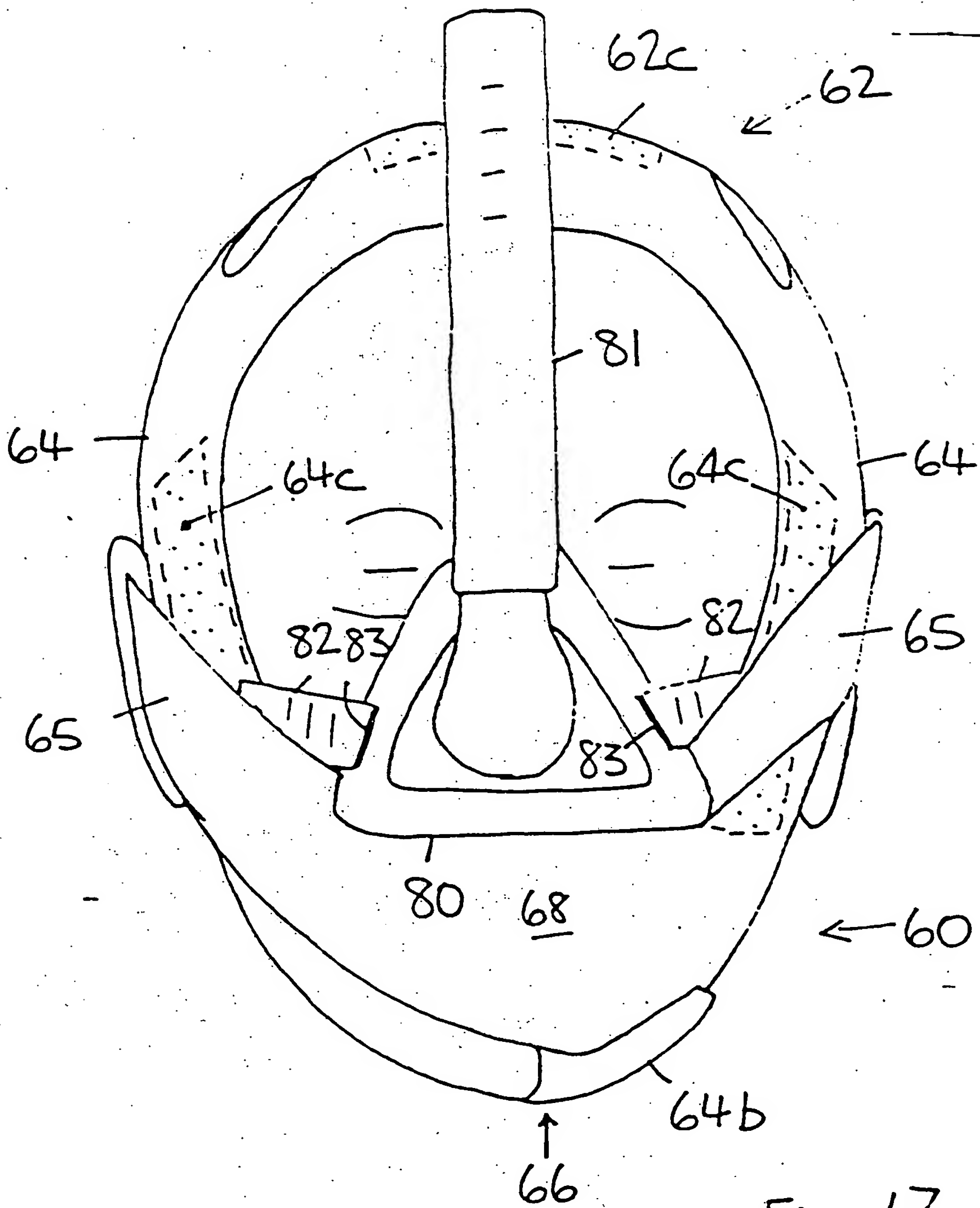


Fig. 17

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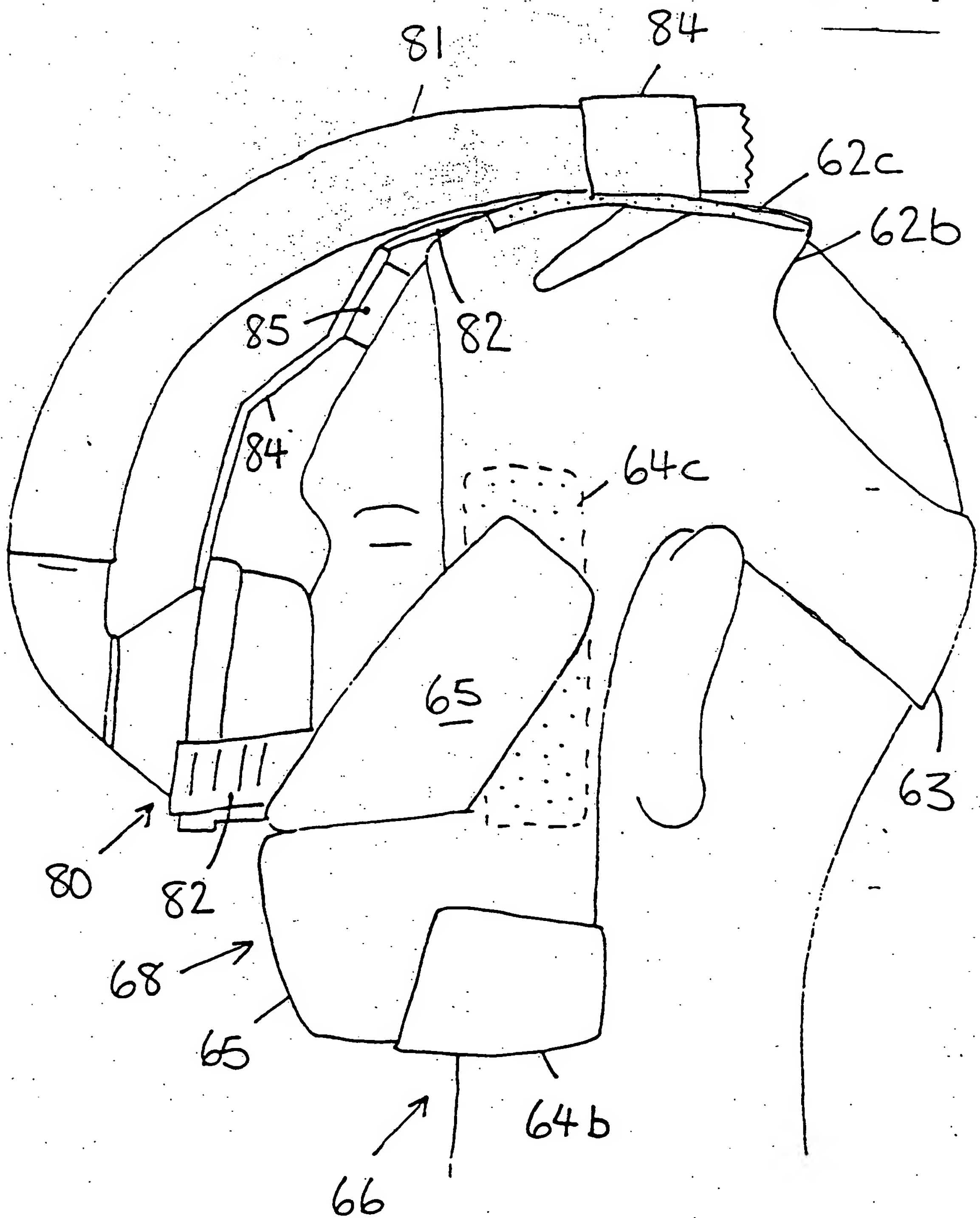


Fig. 18

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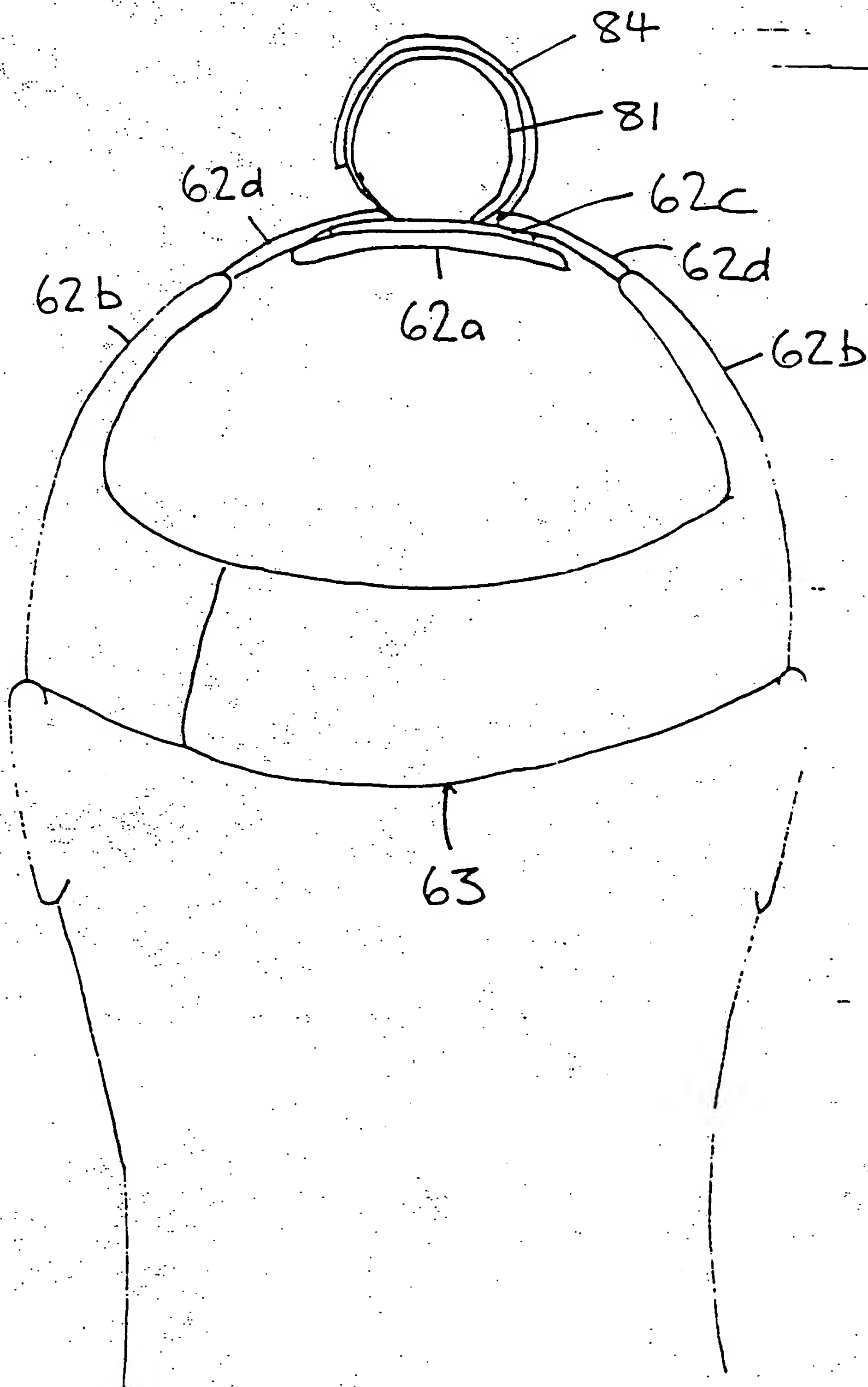


Fig. 19